Second-generation Extensively Porous-coated THA Stems at Minimum 10-year Followup

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Abstract The relatively high prevalence of thigh pain and stress shielding associated with the AML porous-coated cementless femoral component led to the development of the Prodigy[®], a femoral component with more extensive porous-coating and a distal polished bullet tip with medial diaphyseal relief to potentially decrease the flexural rigidity. We prospectively evaluated a cohort of 100 consecutive cementless total hip arthroplasties performed using this device. The minimum followup was 10 years (mean, 11.4 years; range, 10–12 years). At 10-year followup, 69 of the 86 patients (82 hips) were living, 14 patients with 15 hips were deceased, and three patients with three hips were lost to followup. No hips required a stem revision. Two patients (two hips) complained of thigh pain. All hips were bone ingrown. Distal tip radiolucencies and osteolysis occurred in 13 hips (17%) and none, respectively. Twenty-one hips (28%) demonstrated moderate or severe stress shielding. Only further followup will determine if this could be a clinical problem or one with revision surgery. These results encourage the authors to

continue using second-generation extensively coated stems in their primary total hip arthroplasty constructs.

Level of Evidence: Level III, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

Extensively coated femoral components have been used in the total hip arthroplasty construct since the mid 1970s. The AML (DePuy, Warsaw, IN) femoral component became available as a four-fifths coated device with four sizes in 1982. In an attempt to reduce the prevalence of clinical thigh pain (10%–20%) [13, 21] and radiographic stress shielding of bone (18%) [10], the Prodigy[®] femoral component (DePuy, Warsaw, IN) was developed in 1992. This component was more extensively porous-coated than the original AML (along the entire stem excluding the most distal bullet tip, which was polished) and when stem strength allowed, a medial diaphyseal cutout was incorporated to decrease the flexural rigidity of the stem. None of the authors were involved in the development of the component.

We previously reported the outcomes of the Prodigy[®] femoral component at minimum 5 years' followup [8]. Three percent of patients reported thigh pain. All stems had radiographic evidence of bone ingrowth with few radiolucencies around the lower half of the prosthesis as well as less distal femoral lysis.

In a longer term followup of that same cohort we asked whether the device would be durable in terms of revision and survivorship and determined the incidence of thigh pain, bone ingrowth, distal femoral radiolucencies and osteolysis, and stress shielding.

One of the authors (JJC) has received royalties and consulting fees from DePuy (Warsaw, IN), a Johnson & Johnson company. Each author certifies that his institution has approved the reporting of these cases, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Materials and Methods

We prospectively reviewed the first 86 patients (100 hips) who had the Prodigy[®] femoral component implanted from June 1994 to October 1997. This component was made of chromium-cobalt and was a fully coated femoral stem with a 22-mm or 26-mm modular femoral head. These patients were the first in whom the senior author implanted the component and no other cementless stems were used during this time. The Prodigy[®] femoral component was mated with Harris-Galante I acetabular component (68 hips) (Zimmer, Warsaw, IN) or with Duraloc Sector acetabular component (32 hips) (DePuy). At 10 to 12 years following the index THA, 69 patients were alive (82 hips), 14 patients (15 hips) were dead (none of whom had additional operations on their hips), and three patients (three hips) were lost to followup. The minimum clinical followup was 10 years (mean, 11.4 years; range, 10 to 12 years) (Table 1).

The preoperative clinical evaluation included documenting the level of activity, range of motion (ROM) of the hip, level of pain, gait pattern, and level of performance of activities of daily living (ADL), as well as a standard terminology questionnaire [19]. Preoperative diagnosis was primary osteoarthritis (OA) in only 35% of the hips in the original cohort (Table 2).

All surgery was performed by the senior author (JJC). We used a posterolateral approach in all cases. The femoral canal was under-reamed by 0.5 mm to the diameter of the coating of the implant utilized. Intraoperative radiographs were obtained with the broach in place. The canal was machined for a larger size if there was any concern on the intraoperative radiograph that the component would be under-sized.

Table 1. Demographics and followup summary

Variable	Value
Initial cohort	86 patients (100 hips)
Males/females	58/28
Age at index surgery (yrs)	47.7 years (range, 18–72 years)
Died without 10-year data	14 patients (15 hips)
Average radiographic followup	3.1 years (range, 0–8.3 years)
Lost before 10-year followup	3 patients (3 hips)
Cohort with 10-year data	69 patients (82 hips)
Average clinical followup	11.4 years (range, 10–12 years)
Overall	
Minimum 10-year clinical and radiographic data	63 patients (76 hips, 93% of hips in living patients)
Minimum 10-year clinical data only	6 patients (6 hips)

Patients were partial weightbearing with crutches for 6 weeks and then progressed to full weight bearing as tolerated.

The latest followup evaluation was conducted at 10 to 12 years following the index total hip arthroplasty procedure. Patients returned to the clinic for followup or, if they were unable to return, sent current radiographs for evaluation. Patients are routinely followed at 2 year intervals, with closer followup for those with potential concerns such as wear. Early postoperative and interval followup radiographs included anteroposterior projections of the pelvis that included the tip of the femoral prosthesis, and lateral projections of the femur that included the hip. Patients were evaluated in person ($n = 43$) or interviewed by telephone ($n = 26$) using a standard terminology questionnaire for reporting results [19] and completed SF-36 [30], WOMAC [4], Harris hip score [17], and UCLA activity-level scores [3].

Radiographic observations and measurements were based on the anteroposterior radiographs from the early postoperative period and those at latest followup. Among the 69 living patients (82 hips), 63 patients (91%) had a minimum 10-year followup radiograph. Two authors reviewed all radiographs (JJC and DWH), with interpretation reported by consensus. Correction for magnification was completed by standardizing all measurements against the known size of the femoral head.

Femoral component fixation was evaluated for bone ingrowth, stable fibrous fixation, or unstable fibrous fixation according to the criteria of Engh et al. [11]. Femoral component subsidence was determined using the relationship of the top of the lesser trochanter to the medial aspect of the stem collar, defined as a decrease of at least 5 mm (with magnification considered) between the initial postoperative radiograph and those from the last followup [23]. Osteolysis was defined as any nonlinear radiolucency at the

Table 2. Preoperative diagnoses of the Prodigy[®] group

Diagnosis	Patients	Hips
Osteoarthritis	29	35
Avascular necrosis	25	29
Developmental dysplasia	11	13
Legg-Calve-Perthes	6	8
Rheumatoid arthritis	4	4
Traumatic femoral neck fracture	3	3
Slipped capital femoral epiphysis	3	3
Septic arthritis/necrosis	2	2
Anklyosing spondylosis	1	1
Pigmented villonodular synovitis	1	1
Psoriatic arthritis	1	1
Total	86	100

bone-prosthesis interface that was at least 5 mm² according to the seven femoral zones defined by Gruen et al. [15]. Radiolucencies were also recorded according to the seven femoral zones of Gruen [15]. Femoral component stress shielding was defined using a modification of the criteria defined by Engh and Bobyn [10]. Mild stress shielding was limited to the upper 1/3 of the implant, moderate stress shielding extended to the middle 1/3, and severe stress shielding extended below the middle 1/3. Acetabular components were evaluated for bone-prosthesis radiolucencies and acetabular component migration according to the criteria of Massin et al. [25]. The definition of acetabular osteolysis was the same as that of femoral osteolysis.

Kaplan-Meier survivorship analysis [20] was performed for the endpoint of revision for any reason.

Results

Of the original 100 hips, no femoral stems were revised and no hips were revised for aseptic loosening or infection. Fourteen hips were revised at minimum 10-year followup. Ten hips underwent liner exchanges for reasons related to the bearing surface (one of which resulted in an exchange of an ingrown Harris-Galante I acetabular shell). Additionally, two patients had reoperations for periprosthetic femoral fractures with retention of the femoral components. The remaining two hips underwent reoperations for

recurrent dislocation, and were treated by femoral head exchange and acetabular liner exchange to constrained liners. The average time to revision was 7 years (range, 0.2–12.3 years) (Table 3).

Survivorship analysis demonstrated a survival rate (and 95% confidence interval) at 10 years of 88% ± 9% for revision of the hip for any reason (Fig. 1). There was 100% survivorship for femoral component retention and lack of radiographic loosening. Four reoperations occurred more than 10 years following the index surgery (range, 10.1–12.3 years) and all four were liner exchanges for polyethylene wear (Table 3).

Of 86 patients (100 hips), 2% of patients (two patients) reported any thigh pain at last followup. At last followup the average WOMAC score (lower score, higher function) was 14.4 points (range, 0–84.3 points). The average SF-36 physical component summary (PCS) score was 44.9 points (range, 16–61 points). The average SF-36 mental component summary (MCS) score was 54.3 points (range, 28–66). The average Harris hip score was 86 points (range, 36–99) at minimum 10-year followup. The average UCLA activity-level score was 5.9 (range, 2–10).

Radiographic evaluation of the 76 hips with minimum 10-year radiographic followup demonstrated femoral bone ingrowth in all hips. Proximal radiolucencies (zones I and/or VII) occurred in 11% (eight hips), and distal tip radiolucencies (Zone IV) occurred in 17% (13 hips). Proximal femoral osteolysis occurred in 18% (14 hips) and there

Table 3. Summary of revisions

Case	Age* (years)	Gender	Time to revision (years)	Reason for revision	Procedure
1	56	M	0.2	Periprosthetic fracture	ORIF and strut graft of R femur fracture
2	73	M	0.6	Recurrent dislocation	Femoral head exchange and liner exchange to a constrained liner
3	45	M	1.8	Periprosthetic fracture	ORIF
4	64	F	3.4	Polyethylene liner wear	HG-I liner exchange without cementation and femoral head exchange
5	56	M	4.6	Recurrent dislocation	Liner exchange to a constrained liner and femoral head exchange from 26 mm to 32 mm
6	52	F	5.9	Iliac osteolysis with liner wear	Duraloc Sector liner exchange with cementation and femoral head exchange
7	55	F	8.4	Polyethylene liner wear	Deep 62-mm press-fit cup, replacement of femoral head, retained femoral component
8	43	M	8.9	Polyethylene liner wear	HG-I liner exchange with cementation and femoral head exchange
9	43	M	9.9	Liner wear and femoral head metallosis	Exchange to constrained liner, femoral head exchange
10	42	F	9.9	Wear and dissociation of liner	HG-I liner exchange with cementation and femoral head exchange
11	32	M	10.1	Wear and dissociation of liner	HG-I liner exchange with cementation and femoral head exchange
12	26	F	10.4	Wear and dissociation of liner	HG-I liner exchange with cementation and femoral head exchange
13	58	M	10.9	Wear and dissociation of liner	HG-I liner exchange with cementation and femoral head exchange
14	30	M	12.3	Wear and dissociation of liner	HG-I liner exchange with cementation and femoral head exchange

* Age at index surgery.

Fig. 1 Survivorship curve was determined with revision of the hip for any reason as the end point. The probability of survival was 88% at 10 years. The 95% confidence intervals are designated by the dashed lines.

were no cases of distal femoral osteolysis. Femoral stress shielding was mild in 54% (41 hips), moderate in 26% (20 hips), and severe in 1% (one hip). Radiographic evaluation of the acetabular construct demonstrated 21 hips with bone-prostheses radiolucencies, none of which were completely circumferential to include screws signifying loosening, and no components migrated.

For the six living patients who did not achieve a minimum 10-year radiographic followup and for the 14 patients (15 hips) who were deceased at the 10-year followup the average radiographic followup was 6.9 years (range, 5.5–8.8 years) and 3.1 years (range, 0–8.3 years), respectively. All of the hips in these latter two groups demonstrated bony ingrowth and there was no radiographic evidence of loosening of either the femoral or acetabular component, with the exception of a single hip that did not have sufficient radiographic followup for evaluation.

Discussion

Although 90% of four-fifths porous-coated AML femoral components obtained bony ingrowth [12], thigh pain rates of 10% to 20% have been reported [13, 21] as well as 18% of cases with moderate to severe stress shielding [10]. For

this reason the Prodigy[®] femoral component was developed in the hope of decreasing thigh pain by extending the porous coating and incorporating a polished bullet tip, and to decrease stress shielding by providing medial diaphyseal stem relief to decrease the flexural rigidity of the stem. We evaluated the minimum 10-year results of cementless total hip arthroplasty using this second-generation extensively coated femoral prosthesis by specifically determining the need for revision, survivorship, thigh pain, bone ingrowth, distal femoral radiolucencies and osteolysis, and stress shielding.

Our study has the same limitations that all other radiographic studies of hip replacement surgery have. These include inter- and intraobserver variability of radiographic measurements. However, all radiographic findings were agreed upon by two observers. We also acknowledge the difficulty of determining the amount of stress shielding. Determination of stress shielding is somewhat problematic because of the variability of radiographic quality and observer interpretations. However, we used an established grading system that evaluates patterns of bone remodeling [10].

At minimum 10-year followup, no femoral components were revised and there were no revisions for aseptic loosening or infection. There were two revisions for periprosthetic fracture and two for dislocation. The rest of the revisions (10 of 14) were all due to issues related to the bearing surface. It is important to note that the polyethylene used in this series consisted of either gamma-irradiated in air polyethylene (for the 68 HG-I acetabular components) or non-crosslinked polyethylene (for the 32 Duraloc acetabular components). These results are comparable to or better than the results of other cementless hip replacement reports (Table 4) [1, 2, 5, 7, 9, 12, 14, 16, 22, 24, 26–29, 31].

Survivorship in this series was 88% $\pm$ 9% for revision of the hip for any reason and it was 100% when looking at the endpoints of revision for aseptic loosening or radiographic loosening of the femoral component. Once again this is comparable to or better than the results of other cementless hip replacement reports [1, 2, 5, 7, 9, 12, 14, 16, 22, 24, 26–29, 31].

At minimum 10-year results, the authors document bony ingrowth in all cases and a 2% prevalence of thigh pain. This compares favorably not only to the same author's initial experience with a proximally coated chrome cobalt device where the bone ingrowth prevalence was 94% and the thigh pain prevalence was 12%, but also to Engh et al.'s AML results at the same minimum 10-year followup [6, 12, 18, 31] (Table 5). It is important to note that the PCA was designed to fill proximally, had a porous coating different from the AML, was not available in multiple sizes, and is currently no longer available. In addition to the

Table 4. Survivorship and bone ingrowth analysis: comparison of the Prodigy[®] stem with reported results of other cementless stems

Report	Type of stem (cementless)	Revision rate of femoral component for aseptic loosening	Survivorship of femoral component	Thigh pain	Bone ingrowth	Femoral radiolucencies	Femoral osteolysis	Stress shielding
Aldinger et al. [1] (2003)	Cementless Spotorno stem (CLS)	2%	92% at 12 years	0%	99.7%	16% proximal 5% distal	0%	0%
Aldinger et al. [2] (2003)	Cementless Spotorno stem (CLS)	1%	98% at 12 years	0%	99.4%	17% proximal 1.3% distal	0%	0%
Bourne et al. [5] (2001)	Mallory-Head	0%	99% at 10 years		100%		6% proximal	50% mild
Butler et al. [7] (2005)	Zimmer Anatomic Hip	1%	99% at 10 years	0%	91%		10% proximal 1% distal	8.5%
Chen et al. [9] (2006)	Prodigy	1.4%	97.2% at 8 years		99%		5% proximal	16% mod 4% severe
Engel et al. [12] (1997)	AML	1.3%	97% at 12 years	8%	90%			
Grubl et al. [14] (2002)	Protasul 100	0%	99% at 10 years	2%	100%	23% proximal 0% distal	0%	2.4% mild/mod
Ha et al. [16] (2008)	Cementless Anatomic Profile	2%	93% best 58% worst at 10 years	7%	98%	98%	78% proximal 2% distal	
Kubo et al. [22] (2001)	Lord		97% at 10 years		96%			
Marshall et al. [24] (2004)	Integral	1%	98% at 10 years	2.3%	99%		0% distal	
Palm et al. [26] (2002)	Link RS with HA coating vs. noncoated	0% coated 88% non						
Reitman et al. [27] (2003)	Mallory-Head porous	0%	99% at 10 years	4%			8% proximal	
Schramm et al. [28] (2000)	CLS	0%		17%	95%	63% proximal 18% distal		
Trebbse et al. [29] (2005)	Isoelastic RM	39% femoral and/or acetabular	74% at 10 years					
Xenos et al. [31] (1999)	PCA	2%	95% at 10 years	12%	94%		35% proximal 8% distal	
Hennessy et al. (current study, 2009)	Prodigy [®]	0%	100% at 10 years	2%	100%	11% proximal 17% distal	18% proximal 0% distal	27% mod 1% severe

Table 5. Minimum 10-year results of PCA, AML and Prodigy[®] femoral components

Variable	PCA	AML	Prodigy [®]
Femoral revision rate	2% [31]	1.3% [12]	0%
Thigh pain	12% [31]	8% [12]	2%
Bone ingrowth	94% [31]	90% [12]	100%
Femoral radiolucencies	0% proximal [18] 68% distal [18]		11% proximal 17% distal
Femoral osteolysis	35% proximal [31] 8% distal [31]	9.3% proximal [6] 0% distal [6]	18% proximal 0% distal
Stress shielding (moderate or severe)	0% [18]	23% [6]	28%

Fig. 2A–C (A) Preoperative, (B) postoperative, and (C) 10-year followup radiographs show a 39-year-old male patient who underwent THA with a prodigy femoral component at age 28. Presently, he walks miles without assistance, golfs several times a week, and has a

UCLA activity-level score of 7. The radiographs demonstrate bony ingrowth of the stem, moderate stress shielding and a radiodense line in the area of the medial cutout from reaming of the canal.

design, the low thigh pain prevalence may have been related to the fact that, although the present cohort was a consecutive series, it was somewhat selected with patients with poor bone quality receiving cemented stems during the time these stems were implanted. The high percentage of patients with bone ingrowth may be related to the fact that under sizing and malpositioning was eliminated by the use of intraoperative radiographs with the broach in place.

Distal tip radiolucencies occurred in 17%. These did not seem to have any prognostic value given that there was no femoral loosening and no distal tip osteolysis. We attribute the wear of the polyethylene used in this series to the 18% prevalence of proximal femoral osteolysis.

Of interest is the 28% moderate to severe stress shielding observed in this series. Although the presence of stress shielding has not caused major problems at this interval (Fig. 2A–C), only further followup will determine if this could be a clinical problem or a problem with revision surgery.

When comparing these results to those reported for other cementless stems with minimum 10-year followup the fixation is durable, as is the case with most contemporary femoral components (Table 4). This study encourages the senior author to continue to use extensively porous-coated implants in his primary total hip arthroplasty constructs.

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